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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/755,701 | 01/05/2001 | Allan S. Hoffman | UWS 105 | 3998 |

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EXAMINER

TRAN, MY CHAU T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1641

DATE MAILED: 07/16/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/755,701

Applicant(s)

HOFFMAN ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 20-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claim 1-19) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that all the pending claims relate to a conjugate for disrupting a membrane. This is not found persuasive because although there are overlapping features among these inventions, Group I-III, the examination requirement is *not* co-extensive so that an examination for one invention would *not encompass* the limitations of the other inventions thus resulting in divergence of the examination evaluations. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group I would involve a determination of the patentability of the product, which can be made by any method such as a thiol reaction while a patentability determination for Group III would involve a consideration of the patentability of a specific use method other than the methods to recover or identify intracellular components as set forth at page 1, lines 8-10 of the instant specification. These considerations are very different in nature.

The requirement is still deemed proper and is therefore made **FINAL**.

1. Claims 20-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

2. **Applicants are advised that if the product claim (Group I) is elected then in** accordance with the court decisions in *In re Ochiai*, {71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir.

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1995)} and *In re Brouwer* {77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996)}, in the event that a product claim (Group I) is found to be allowable, a method of use claim (Group III) and method of making claim (Group II), *which is of the same scope as the allowed product claim*, may be rejoined with the allowed product claim.

Information Disclosure Statement

3. In accordance with the duty to disclose applicant is requested to provide an IDS.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the claims do not correspond with the enabling written description of the invention as it is set forth in the specification and figures. The enabling description of the invention clearly requires the hydrophilic component to a polyalkylene glycol or a polyalkylene oxide (see pg. 21, lines 1-11). Claim 1 step "b" as presently written includes biological hydrophilic agents such as cysteine or serine amino acids. The specification clearly does not support a claim of this scope with an enabling written description.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) The term “hydrophilic agent” in Claim 1 is vague and indefinite because it is unclear what type of effect this “agent” is producing. Physical? Chemical? Or Biological?
- b) Claims 1 and 2 contain improperly written Markush language. When using the phrase “selected from the group consisting of”, “and” is included not “or”.
- c) The phrase “a therapeutic, diagnostic or prophylactic agent” of Claim 2 is vague and indefinite because it is unclear how it is correlated with the hydrophilic component. Is it required to be attached to the conjugate or encapsulated in the polymer?

8. It is noted that from the specification and examples that the invention appears to be directed to a composition comprised of polyethylene glycol (PEG) with an acetal linkage which can be “cleave^λ as a function of pH” as required elements.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al. (US Patent 6,210,717 B1).

Choi discloses a composition for delivering a selected nucleic acid and various kinds of ligands into a targeted host cell (Abstract). The composition is a copolymer transport molecule that is comprise of a hydrophilic portion and a hydrophobic portion (col. 2, lines 29-55; col. 3, lines 12-26; col. 4, lines 60-62). An amide linkage can bond these portions or the copolymer is a graft of a hydrophobic polyester portion or a hydrophilic cation portion.

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Choi differs from the instant invention in failing to explicitly disclose that linkage can be cleaved by a function of pH.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the linker (amide or ester) of Choi be cleav^d as a function of pH. These types of linkers are the same ^{as} ~~to~~ those disclos^d in the specification (pg. 23, lines 3-10) and therefore the prior art linkers are also pH cleavable. A skilled artisan would have had a reasonable expectation of success in cleaving the linkers as taught by Choi as a function of pH because these linkers are functionally equivalent.

13. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US Patent 5,939,453).

Heller discloses a composition that is block copolymers having both hydrophilic and hydrophobic blocks (Abstract). This composition provides a pharmaceutical delivery system or for the sustained release of an active agent (col. 4, lines 1-11). The hydrophilic block ^{is} ~~is~~ PEG (polyethylene glycol) and the hydrophobic block is POE (poly(orthoester)), which is bioerodible (col. 5, lines 10-17). Bioerodible refer^s to the degradation, disassembly or digestion of the polymer by action of the biological environment, which includ^es physiological pH.

Heller differs from the instant invention in failing to explicitly disclose that linkage of the hydrophilic and can be cleaved by a function of pH.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the linker (ester) of Heller be cleav^d as a function of pH. This type of linker is the same ^{as} ~~to~~ those disclos^d in the specification (pg. 23, lines 3-10) and therefore the prior art

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linkers are also pH cleavable. A skilled artisan would have had a reasonable expectation of success in cleaving the linker as taught by Heller as a function of pH because these linkers are functionally equivalent.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct
July 12, 2002


MARY E. CEPERLEY
PRIMARY EXAMINER